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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/911,047	ERIKSON ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/01; 5/02; 1/03; 4/02; 7/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 3 October 2003 in which a terminal disclaimer was submitted. The disclaimer has been reviewed and entered.

The previous rejections under obviousness-type double patenting are withdrawn in view of the terminal disclaimer.

The examiner for this application has changed. Please address future correspondence to Examiner BJ Forman, Art Unit: 1634.

New grounds for rejection are discussed.

Claims 1-29 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-26 are indefinite in Claim 1 because the claim recites "wherein...said first stimulus, said second stimulus, said first signal, and said second signal are electromagnetic

radiation.....and when said first stimulus and said second stimulus are electronic radiation, said first signal and said second signal are electric current." The first portion of the above, requires the first and second signals to be electromagnetic radiation. However, the second portion of the above, requires the first and second stimuli to be electronic radiation and the first and second signal to be electric current. Hence, the two portions of the recitation contradict because electromagnetic radiation signals cannot also be electric current.

For purposes of examination, the claim is interpreted as requiring either 1) first stimulus, said second stimulus, said first signal, and said second signal are electromagnetic radiation **or** 2) first and second stimuli are electronic radiation and first and second signal are electric current

Claims 27-29 are indefinite in Claim 27 for the same reasons stated above regarding Claim 1.

Claim 24 is indefinite for the recitation "said first signal, said second signal and at least one additional signal is **applied**" because the recitation lacks proper antecedent basis in Claims 1 and 22 wherein the stimuli are applied and the signals are detected.

Claim 25 is indefinite for the recitation "said first signal and said second signal is **applied**" because the recitation lacks proper antecedent basis in Claim 1 and wherein the stimuli are applied and the signals are detected.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-6, 8, 11, 17-18, 20, 22, 24-25, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Kukreti et al (Nucleic Acids Research, 1997, 25(21): 4264-4270).

Regarding Claim 1, Kukreti et al disclose the method of assaying sequence-specific hybridization comprising combining a biopolymer target and biopolymer probe to provide a test sample, applying a first stimulus (spectrophotometer illumination) to the test sample, detecting a first signal from the test sample (spectrophotometer detection), applying a second stimulus (spectrophotometer illumination) to the test sample, detecting a second signal from the test sample(spectrophotometer detection) and comparing the first and second signals to accomplish the assaying wherein at least one label is provided in the sample (page 4265, left column, second full paragraph "oligonucleotides") and first and second stimulus and first and second signals are electromagnetic (page 4265, left column, last paragraph-right column first and second paragraphs) and wherein the method comprises an intermediate electronic stimulus (i.e. electronically applied heat via Haake PG20). Kukreit et al teach their method of sequence-specific hybridization via melting analysis wherein every 8 minutes the sample is stimulated and detected via the spectrophometer during the heating from 0° C to 80° C using the Haake PG20 thermoprogrammer as illustrated in Fig. 2. Hence, they stimulate and detect using electromagnetic radiation with intermediate electronic stimulus as claimed.

Regarding Claim 2, Kukreit et al disclose the method wherein the first stimulus is photonic (spectrophotometer illumination) and the second stimulus is electronic (i.e. electronically applied heat via Haake PG20).

Regarding Claim 3, Kukreit et al disclose the method wherein the first and second stimulus is photonic (spectrophotometer illumination) (page 4265, left column, last paragraph-right column first and second paragraphs).

Regarding Claim 4, Kukreit et al disclose the method wherein the first stimulus is electronic (i.e. electronically applied heat via Haake PG20) and the second stimulus is photonic (spectrophotometer illumination).

Regarding Claim 5, Kukreit et al disclose the method wherein the first and second stimuli are electronic (i.e. electronically applied heat via Haake PG20).

Regarding Claim 6, Kukreit et al disclose the method wherein application of first and second stimuli is at least "partially coextensive" i.e. the electronically applied heat is continuously applied (page 4265, left column, last paragraph-right column first paragraph).

Regarding Claim 8, Kukreit et al disclose the method wherein the first and second signals are photonic (page 4265, left column, last paragraph-right column, first paragraph).

Regarding Claim 11, Kukreit et al disclose the method wherein the electromagnetic radiation is photonic (page 4265, left column, last paragraph-right column, first paragraph).

Regarding Claim 17, Kukreit et al disclose the method wherein the probe and target contain nucleobases and hybridize to form a duplex i.e. the triplex of Kukreit comprises a duplex (page 4265, left column, last paragraph-right column, first paragraph and Fig. 2).

Regarding Claim 18, Kukreit et al disclose the method wherein the probe and target contain nucleobases and hybridize to form a triplex (page 4265, left column, last paragraph-right column, first paragraph and Fig. 2).

Regarding Claim 20, Kukreit et al disclose the method wherein the probe is a nucleic acid analog comprising a cationic moiety (page 4265, Fig. 1).

Regarding Claim 22, Kukreit et al disclose the method further comprising applying at least one additional stimulus, detecting at least one additional signal and comparing the first, second and additional signals to accomplish the assaying i.e. the signal is detected every eight minutes during application of heat (page 4265, left column, last paragraph-right column, first paragraph and Fig. 2).

Regarding Claim 24, as stated above, the claim is indefinite for the recitation "signal is applied". For purposes of examination, the claim is interpreted as "signal is detected". This interpretation properly depends from Claims 1 and 22 wherein the signals are detected. Kukreit et al detect a signal every 8 minutes thereby detecting the first and second signals non-continuously by (page 4265, left column, last paragraph-right column, first paragraph and Fig. 2).

Regarding Claim 25, as stated above, the claim is indefinite for the recitation "signal is applied". For purposes of examination, the claim is interpreted as "signal is detected". This interpretation properly depends from Claim 1 wherein the signals are detected. Kukreit et al detect a signal every 8 minutes thereby detecting the first and second signals non-continuously by (page 4265, left column, last paragraph-right column, first paragraph and Fig. 2).

Regarding Claim 27, Kukreti et al disclose the method of assaying sequence-specific hybridization comprising adding a biopolymer target and biopolymer probe to a binding medium to provide a test sample (i.e. hybridization buffer, page 4265, right column, lines 6-13), applying a first stimulus (spectrophotometer illumination) to the test sample, detecting a first signal from the test sample (spectrophotometer detection), applying a second stimulus (spectrophotometer illumination) to the test sample, detecting a second signal from the test sample(spectrophotometer detection) and comparing the first and second signals to accomplish the assaying wherein at least one label is provided in the sample (page 4265, left column, second full paragraph "oligonucleotides") and first and second stimulus and first and second signals are electromagnetic (page 4265, left column, last paragraph-right column first

and second paragraphs) and wherein the method comprises an intermediate electronic stimulus (i.e. electronically applied heat via Haake PG20). Kukreit et al teach their method of sequence-specific hybridization via melting analysis wherein every 8 minutes the sample is stimulated and detected via the spectrophometer during the heating from 0° C to 80° C using the Haake PG20 thermoprogrammer as illustrated in Fig. 2. Hence, they stimulate and detect using electromagnetic radiation with intermediate electronic stimulus as claimed.

6. Claims 1, 6, 10-11, 13-14, 17, 20, 26-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Megerle (U.S. Patent No. 6,391,624, filed 2 June 2000 with priority to provisional application 60/137,597, filed 3 June 1999).

Regarding Claim 1, Megerle discloses the method of assaying sequence-specific hybridization comprising combining a biopolymer target and biopolymer probe to provide a test sample, applying a first stimulus to the test sample, detecting a first signal from the test sample, applying a second stimulus to the test sample, detecting a second signal from the test sample and comparing the first and second signals to accomplish the assaying wherein at least one label is provided in the sample and first and second stimulus are electronic radiation and the first and second signals are electric current (Column 7, lines 13-58 and Column 10, line 53-Column 11, line 37).

Regarding Claim 6, Megerle discloses the method wherein application of first and second stimuli is at least "partially coextensive" (Column 11, lines 3-10).

Regarding Claim 10, Megerle discloses the method wherein the first and second signals are electronic (Column 10, line 53-Column 11, line 37).

Regarding Claim 11, Megerle discloses the method wherein the electromagnetic radiation is electronic radiation (Column 11, lines 3-10).

Regarding Claim 13, Megerle discloses the method wherein the electronic radiation is voltage (Column 11, lines 3-10).

Regarding Claim 14, Megerle discloses the method wherein at least one label transfers energy to another label (Column 7, lines 54-58 and Column 10, lines 53-65).

Regarding Claim 17, Megerle discloses the method wherein the probe and target contain nucleobases and hybridize to form a duplex (Column 7, lines 13-58).

Regarding Claim 20, Megerle discloses the method wherein the probe is a nucleic acid analog comprising a nucleobase analog (Column 9, lines 57-63 and Fig. 4-5).

Regarding Claim 26, Megerle discloses the method wherein the probe is bonded to a substrate (Column 7, lines 13-58 and Fig. 2).

Regarding Claim 27, Megerle discloses the method of assaying sequence-specific hybridization comprising adding a biopolymer target and biopolymer probe to a binding medium to provide a test sample (Fig. 2), applying a first stimulus to the test sample, detecting a first signal from the test sample, applying a second stimulus to the test sample, detecting a second signal from the test sample and comparing the first and second signals to accomplish the assaying wherein at least one label is provided in the sample and first and second stimulus are electronic radiation and the first and second signals are electric current (Column 7, lines 13-58 and Column 10, line 53-Column 11, line 37).

7. Claims 1, 6, 11-17, 21-22, 24-25, 27-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Zenhausern (U.S. Patent Application Publication No. 2002/0094531, filed 14 June 1999).

Regarding Claim 1, Zenhausern disclose the method of assaying sequence-specific hybridization comprising combining a biopolymer target and biopolymer probe (primer) to provide a test sample, applying a first stimulus to the test sample, detecting a first signal from the test sample, applying a second stimulus to the test sample, detecting a second signal from the test sample and comparing the first and second signals to accomplish the assaying wherein at least one label is provided in the sample (¶ 73-75) and first and second stimulus and first and second signals are electromagnetic (¶ 77) and wherein the method comprises an intermediate electronic stimulus (i.e. electronically applied heat via Peltier element).

Regarding Claim 6, Zenhausern discloses the method wherein application of first and second stimuli is at least "partially coextensive" (i.e. real-time ¶ 77).

Regarding Claim 11, Zenhausern discloses the method wherein the electromagnetic radiation is electronic radiation or photonic radiation (¶ 77, lines 1-8).

Regarding Claim 12, Zenhausern discloses the method wherein the photonic radiation is laser (¶ 77, lines 1-8).

Regarding Claim 13, Zenhausern discloses the method wherein the electronic radiation is voltage i.e. power supply (¶ 77, lines 1-8).

Regarding Claim 14, Zenhausern discloses the method wherein the label transfers energy i.e. volatile tags (¶ 34).

Regarding Claim 15, Zenhausern discloses the method wherein the label is chemiluminescent or electrochemiluminenscent (¶ 34).

Regarding Claim 16, Zenhausern discloses the method wherein the label is chemiluminescent or electrochemiluminenscent (¶ 12 and 34).

Regarding Claim 17, Zenhausern discloses the method wherein discloses the method wherein the probe (primer) and target contain nucleobases and hybridize to form a duplex (¶ 77).

Regarding Claim 21, Zenhausern discloses the method wherein at least one of the probe or target comprises an amino acid sequence (¶ 26 and 32).

Regarding Claim 22, Zenhausern discloses the method further comprising applying at least one additional stimulus to the sample i.e. "real-time" monitoring (¶ 76-77).

Regarding Claim 24, Zenhausern discloses the method wherein the signals are detected non-continuously i.e. at different cycles (Fig. 2).

Regarding Claim 25, Zenhausern discloses the method wherein the signals are detected non-continuously i.e. at different cycles (Fig. 2).

Regarding Claim 27, Zenhausern disclose the method of assaying sequence-specific hybridization comprising combining a biopolymer target and biopolymer probe (primer) in a binding medium (i.e. PCR buffer) to provide a test sample, applying a first stimulus to the test sample, detecting a first signal from the test sample, applying a second stimulus to the test sample, detecting a second signal from the test sample and comparing the first and second signals to accomplish the assaying wherein at least one label is provided in the sample (¶ 73-75) and first and second stimulus and first and second signals are electromagnetic (¶ 77) and wherein the method comprises an intermediate electronic stimulus (i.e. electronically applied heat via Peltier element).

Regarding Claim 28, Zenhausern discloses the method wherein at least one of the probe or target is a protein, peptide or lipid (¶ 26 and 32).

Regarding Claim 29, Zenhausern discloses the method wherein at least one of the probe or target is not a biopolymer e.g. cell, cell wall, virus (¶ 26 and 32).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2-5, 7-10, 23, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zenhausern (U.S. Patent Application Publication No. 2002/0094531, filed 14 June 1999).

Regarding Claims 2-5, 7-10 and 23, Zenhausern teach the method of assaying sequence-specific hybridization comprising combining a biopolymer target and biopolymer probe (primer) to provide a test sample, applying a first stimulus to the test sample, detecting a first signal from the test sample, applying a second stimulus to the test sample, detecting a second signal from the test sample and comparing the first and second signals to accomplish the assaying wherein at least one label is provided in the sample (¶ 73-75) and first and second stimulus and first and second signals are electromagnetic (¶ 77) and wherein the method comprises an intermediate electronic stimulus (i.e. electronically applied heat via Peltier element).

Zenhausern teach the method wherein the stimulus and the signal are electromagnetic i.e. photonic and/or electronic (¶ 77). Furthermore, they teach the heating (i.e. stimulus) for the PCR reaction is provided by any of many known electromagnetic means (¶ 79). While they do not teach the specific combinations of photonic and electronic stimuli and signals, their teaching clearly suggests their use and combination. Furthermore, the teaching of Zenhausern suggests that their photonic and electronic stimuli and signals functional equally to stimulate and detected reactions.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the electromagnetic stimuli and detection of Zenhausern in the claimed combinations based on experimental design and desired detection.

The courts have stated with regard to functional similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904).

10. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zenhausern (U.S. Patent Application Publication No. 2002/0094531, filed 14 June 1999) in view of Mazumder et al (Biochemistry, 1996, 35: 13762-13771) and Durland et al (Biochemisty, 1991, 30: 9246-9255).

Regarding Claims 18-20, Zenhausern teach the method of assaying sequence-specific hybridization as discussed above but they do not teach the probe and target form a duplex or triplex and they do not teach the probe comprises a cationic moiety.

However, triplex and quartet formation were well known in the art at the time the claimed invention was made. Mazumder teaches that quartet structures function as inhibitors (Abstract) and Durland teaches that cationic-moiety-containing probes form triplexes with double-stranded DNA to identify site-specific double-stranded DNAs under physiological conditions (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the triplex and quartet formations of Durland and Mazumder et al to the probe-target complex of Zenhausern for the expected benefit of identifying inhibitors and site-specific double stranded DNA as taught by Durland and Mazumder et al.

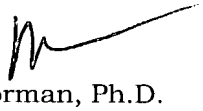
Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
April 7, 2004